

Applicants: Rolland-Yves MAUVERNAY  
Serial No.: 09/807,586

A 2 16. (New) Flexible impervious bag for medical use containing a pharmaceutical preparation of oxaliplatinum according to claim 10, wherein said flexible bag is multi-compartmented.

17. (New) Flexible impervious bag for medical use containing a pharmaceutical preparation of oxaliplatinum according to claim 10, wherein said solution has a pH of 4.5 to 6.0, a concentration of oxaliplatinum in the preparation of at least 95% of the initial concentration, as well as a clear, colorless appearance free from precipitate after storage for a pharmaceutically acceptable period.

REMARKS

The Examiner has objected that the application does not contain an abstract of the disclosure. An abstract is provided herewith as required by 37 CFR 1.72(b).

The applicant wishes to fully cooperate with the Examiner with respect to the presence of any errors in the specification. Respectfully, applicant has not found errors in the specification but has instead concentrated on clearly delimiting the claims.

Claims 4-9 are objected to under 37 CFR 1.65(c) as being in improper form because a multiple dependent claim. New claims 13-17 have been duly amended so as to eliminate their multiple dependency.

Claims 1-3 are rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject-matter which applicant regards as the invention.

This rejection is respectfully traversed.

Applicants: Rolland-Yves MAUVERNAY  
Serial No.: 09/807,586

New claims 10, 11 and 12 have been redrafted in order to clearly indicate that the subject-matter which the applicant regards as the invention is a flexible impervious bag constructed from plastic material and containing a pharmaceutical preparation of liquid oxaliplatinum, with the very important proviso that any portion of the bag in direct contact with the liquid oxaliplatinum does not contain polyvinylchloride-based plastic material.

The proviso will be discussed in further detail below.

Claims 2 and 3 have been redrafted as claims 11 and 12 in order to rectify the problems of insufficient antecedent basis.

It is respectfully submitted that the claims as amended are in proper form and thus the rejection under 35 U.S.C. §112, 2<sup>nd</sup> paragraph should be withdrawn.

Claim 1 is rejected under 35 U.S. C. §102(b) as being anticipated by U.S. 5,716,988.

This rejection is respectfully traversed.

The cited U.S. patent is in fact an earlier application of the present assignee. This U.S. patent '988 in fact corresponds to the International Patent Application W096/04904 already cited at page 1 of the present specification.

It is immediately clear to the person skilled in the art that U.S. '988 only describes the pharmaceutical preparation of oxaliplatinum itself.

However, it makes no mention of the specific structure or material from which a flexible impervious bag for containing said pharmaceutical preparation could be made.

The only references to packaging of the pharmaceutical preparation can be found at column 2, line 61 (where mention is made of a flexible pouch).

Applicants: Rolland-Yves MAUVERNAY  
Serial No.: 09/807,586

Absolutely no mention is made in U.S. '988 of the extremely important fact that oxaliplatinum in aqueous solution cannot tolerate being in contact with polyvinylchloride-based materials.

In conclusion, it should be noted that U.S. '988 only discloses a pharmaceutical preparation of an oxaliplatinum solution, which can be contained in a flexible pouch.

Claim 1 of the present invention specifies the nature of said flexible pouch. The fact that said flexible pouch is made of plastic, and that, for the layers in contact with the preparation, said plastic should not be PVC, leads to greater stability of the pharmaceutical preparation which is thus not adulterated, since the oxaliplatinum is not in contact with PVC chlorine atoms. Moreover, using materials other than PVC confers improved liquid-tightness on the flexible pouch and enables it to be used immediately, without other modifications.

Since these aspects have not been disclosed in or suggested by the prior art, the subject-matter of the claims is indeed considered to be novel over U.S. '988.

It is hence respectfully submitted that the flexible impervious bag described in new claim 10 is indeed novel over the cited prior art and hence the rejection under 35 U.S.C. §102(b) should be withdrawn.

Claims 1-3 are rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. '988.

This rejection is respectfully traversed.

As already mentioned above, absolutely no mention is made in U.S. '988 of the importance of having a flexible impervious bag wherein any portion of the bag in direct contact with the pharmaceutical preparation of oxaliplatinum does not contain polyvinylchloride-based plastic material.

Applicants: Rolland-Yves MAUVERNAY  
Serial No.: 09/807,586

Furthermore, as admitted by the Examiner, the reference does not make any mention to the multi-layers structure of the bag or its material.

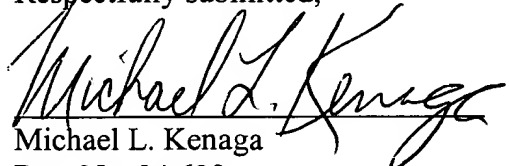
Contrary to what the Examiner indicates, superior and unexpected results indeed show the criticality of such a bag since it is indicated in the present specification, at page 4, line 23 and following, page 5, line 8 and following and at page 5 again, line 20 and following, that the flexible bags of the present invention as opposed to flexible bags containing PVC have better water permeability properties, are more impervious, and have a better impermeability to oxygen.

Thus, it would not at all have been obvious to the person skilled in the art to provide oxaliplatinum in the flexible container as taught by the present specification and claims.

The Examiner finally indicates that U.S. 6,306,902 discloses stable oxaliplatinum formulation. This reference is not any more pertinent than the U.S. '988 reference, insofar as it actually concerns the oxaliplatinum preparation itself and not the bag or packaging in which it is contained.

In view of the foregoing, it is respectfully submitted that the rejection under 35 U.S.C. §103(a) be withdrawn and the present application is in form for allowance.

Respectfully submitted,

  
Michael L. Kenaga  
Reg. No. 34,639

**Piper Rudnick**  
P.O. Box 64807  
Chicago, IL 60664-0807  
Phone: (312) 368-4000  
Fax: (312) 236-7516



28465

PATENT TRADEMARK OFFICE